Before the FEDERAL COMMUNICATIONS COMMISSION Washington, D.C. 20554

In the Matter of)	
)	
Amendment of Parts 2 and 95 of the Commission's	s)	ET Docket No. 09-36
Rules to Provide Additional Spectrum for the)	
Medical Device Radiocommunication Service in)	RM-11404
the 413-457 MHz Band)	

REPLY COMMENTS

THE ALFRED MANN FOUNDATION

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SUMMARY

The record developed in this proceeding reflects overwhelming support for Commission adoption of service and technical rules allowing medical micropower network ("MMN") operation in the 413-457 MHz band on a secondary basis. The parties supporting MMN rules represent a broad spectrum of interests, including Congressional leaders, government agencies, veterans organizations, medical research and treatment establishments, non-profit organizations, private industry (including equipment manufacturers and pharmaceutical companies), doctors, scientists, and individuals with disabilities. Even the few parties opposing the Commission's proposal concede that MMNs offer invaluable public interest benefits.

Contrary to MMN opponents' unsubstantiated claims, both the Commission and the scientific community have found the 413-457 MHz band to be within the narrow range of spectrum that is most suitable for radiofrequency ("RF") signal propagation within the human body. Moreover, contrary to MMN opponents' speculation, restricting MMN operations solely or even primarily to wireless medical telemetry service spectrum ("WMTS") in the 608-614 MHz band and Part 90 medical telemetry spectrum above 450 MHz would render the devices inoperable due to RF congestion and incumbent high power operations on and adjacent to these frequencies. Because of the significant technical differences between medical telemetry and MMN devices, revising the WMTS and Part 90 rules to accommodate both types of equipment would be infeasible, if not impossible.

Furthermore, despite MMN opponents' unfounded claims of harmful interference between MMNs and incumbent services, numerous MMN operational factors and techniques serve to mitigate potential interference both from and to incumbent services. AMF expects to demonstrate in the near term the effectiveness of these factors and techniques through

comprehensive interference analysis and, if required, testing to be conducted jointly with the Joint Spectrum Center, a field office within the U.S. Defense Spectrum Organization.

Because multiple competing suppliers may offer different MMN devices, the Commission should adopt a minimum set of technical requirements designed to ensure RF compatibility between different MMN systems, as well as between MMNs and incumbent systems. Conversely, the Commission should reject any proposed rules that would create an unmanageable RF interference environment. AMF's proposed MMN rules strike a proper balance between allowing flexible spectrum use and ensuring effective interference mitigation, and thus should be adopted.

Prompt Commission action in this proceeding is critical to the commercial deployment of a pioneering technology that promises to transform the treatment and care of millions of Americans with disabilities. AMF expects to commence initial human trials using MMN devices next year, and the ultimate success of these trials will depend largely upon the regulatory certainty that only the Commission can provide.

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REPLY COMMENTS

The Alfred Mann Foundation for Scientific Research ("AMF") submits these reply comments regarding the notice of proposed rulemaking in the above-captioned proceeding to allow medical micropower network ("MMN") use of spectrum in the 413-457 MHz frequency band on a secondary basis.¹

I. THE PUBLIC INTEREST BENEFITS OF MMNs ARE UNDISPUTED

More than 50 parties representing a broad spectrum of interests, including Congressional leaders, government agencies, veterans organizations, medical research and treatment establishments, non-profit organizations, private industry (including equipment manufacturers and pharmaceutical companies), doctors, scientists, and individuals with disabilities, filed comments strongly supporting the Commission's proposed rules to allow medical micropower network ("MMN") devices in the 413-457 MHz band. These parties unanimously agree that

¹ See Amendment of Parts 2 and 95 of the Commission's Rules to Provide Additional Spectrum for the Medical Device Radiocommunication Service in the 413-457 MHz Band, Notice of Proposed Rulemaking, ET Dkt. No. 09-36, RM-11404, FCC No. 09-20, (Mar. 20, 2009) ("NPRM"). All documents filed in these proceedings: 09-36 and RM-11404, will be short cited herein.

MMNs offer extraordinary health and public interest benefits that cannot be achieved with existing commercially available technologies.

For example, veterans service organizations, such as the Paralyzed Veterans of America ("PVA"), asserted that MMN technology "holds exceptional therapeutic promise previously unattainable for millions of Americans, including US military service personnel and veterans, living with sensory and motor dysfunction due to injury or disease." They further declared that "[i]t is our nation's responsibility to ensure U.S. service men and women have access to new medical technologies that would allow them to continue serving and to lead productive lives long after their service terms have ended."

Additionally, leading doctors and scientists from government organizations, such as the National Institute on Disability and Rehabilitation Research ("NIDRR") and the Hines Veterans Administration Hospital, noted that the "hope that the MMN equipment brings cannot be underestimated" and that "MMN technology represents a true medical breakthrough and can offer incalculable benefits not available through any other medical treatment option." Similarly, doctors and scientists in academia and the private sector, many of whom have decades of experience in the research and treatment of neuromuscular injuries and conditions, observed that MMN devices "can be used to treat a broad range of injuries and conditions, including stroke, severe spinal cord and brain injuries, debilitating disorders such as cerebral palsy and

² Letter from Thomas E. Stripling, PVA, to Marlene H. Dortch, Sec'y, FCC, at 2 (Sept. 4, 2009).

³ See Letter from General Al Gray, USMC (Ret), Chairman, Injured Marine Semper Fi Fund, to Marlene H. Dortch, Sec'y, FCC, at 1 (July 9, 2009), available at http://fjallfoss.fcc.gov/prod/ecfs/retrieve.cgi?native_or_pdf=pdf&id_document=7019915752; Letter from Major General J. Michael Myatt, USMC (Ret), President and CEO, Marines' Mem'l Ass'n, to Marlene H. Dortch, Sec'y, FCC, at 1 (July 6, 2009).

⁴ See Letter from James S. Walter, Ph.D., Edward Hines, Jr. Hosp., U.S. Dep't of Veterans Affairs, to Marlene H. Dortch, Sec'y, FCC, at 1 (Aug. 11, 2009); Letter from Arthur M. Sherwood, P.E., Ph.D., NIDRR, to Marlene H. Dortch, Sec'y, FCC, at 1 (Aug. 11, 2009).

osteoporosis, and more common afflictions such as arthritis and headache."⁵ They recognized that "the available medical treatment options are limited, and the demand for better, more effective options continues to grow as these injuries and conditions take their toll on an increasing number of people."⁶ They also agreed that MMN devices "provide a safer, less invasive, more convenient, and more effective treatment option than existing alternatives."⁷

Notably, individuals who have received predecessor MMN or other implant devices that perform functional electric stimulation ("FES") personally attested to the powerful impact of those devices on their everyday lives. One person stated that these devices allowed her "to stand

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⁵ See, e.g., Letter from Alan D. Grinnell, Distinguished Professor, UCLA, to Marlene H. Dortch, Sec'y, FCC, at 1 (Aug. 11, 2009); Letter from J. Thomas Mortimer, Ph.D., Professor Emeritus, Case Western Reserve Univ., to Marlene H. Dortch, Sec'y, FCC, at 1 (July 29, 2009); V. Reggie Edgerton, Ph.D., Professor, UCLA, to Marlene H. Dortch, Sec'y, FCC, at 1 (Aug. 11, 2009); Letter from Dr. Adrian R.M. Upton, Professor, McMaster Univ., to Marlene H. Dortch, Sec'y, FCC, at 1 (Aug. 11, 2009); Letter from Andrew B. Schwartz, Ph.D., Univ. of Pittsburgh, to Marlene H. Dortch, Sec'y, FCC, at 1-2 (Aug. 11, 2009); Letter from Robert A. Stevenson, PE, Senior Scientist, Greatbatch Med., to Marlene H. Dortch, Sec'y, FCC, at 1 (Aug. 11, 2009).

⁶ See, e.g., Dr. Dianne Van Hook, Chancellor, College of the Canyons, to Marlene H. Dortch, Sec'y, FCC, at 1 (Aug. 11, 2009); Letter from David P. White, M.D., Professor, Harvard Med. School, to Marlene H. Dortch, Sec'y, FCC, at 1 (Aug. 11, 2009); Letter from Stuart Binder-Macleod, Ph.D., Professor and Chair, Univ. of Del., to Marlene H. Dortch, Sec'y, FCC, at 1 (Aug. 11, 2009); Letter from Dominique M. Durand, Ph.D., Case Western Reserve Univ., to Marlene H. Dortch, Sec'y, FCC, at 1 (Aug. 11, 2009); Letter from Robert R. Myers, Ph.D., UCSD, to Marlene H. Dortch, Sec'y, FCC, at 1 (Aug. 11, 2009); Letter from Prof. Yitzhak Apeloig, President, Technion – Israel Inst. of Tech., to Marlene H. Dortch, Sec'y, FCC, at 1 (Aug. 11, 2009).

⁷ See, e.g., Letter from Charles C. Finley, Ph.D., Assoc. Professor, UNC School of Med., to Marlene H. Dortch, Sec'y, FCC, at 2 (Aug. 11, 2009); Letter from Blake Wilson, Co-Dir., Duke Hearing Ctr., Duke Univ. Med. Ctr., to Marlene H. Dortch, Sec'y, FCC, at 1 (Aug. 11, 2009); Letter from Gad Alon, Ph.D., PTRS-Univ. of Md. School of Med., to Marlene H. Dortch, Sec'y, FCC, at 2 (Aug. 11, 2009); Letter from Ross Davis, MD, Neural Eng'g Clinic, to Marlene H. Dortch, Sec'y, FCC, at 1 (Aug. 11, 2009); Letter from Mark A. Liker, MD, Asst. Professor, Brain & Spine Ctr., USC Keck School of Med., to Marlene H. Dortch, Sec'y, FCC, at 1 (Aug. 12, 2009).

with a walker,"⁸ while another asserted that he "was able to hug my wife with both arms for the first time in over four years (since I had my stroke)."⁹

Even commenters opposing the Commission's proposed MMN rules acknowledge the invaluable public interest benefits that MMNs offer. For example, Motorola Inc. ("Motorola") affirmed that MMN "is an exciting technology that deserves the FCC's full attention and consideration for new spectrum allocations." The Society of Broadcast Engineers, Inc. ("SBE") also noted that MMN devices "offer the possibility of more effective treatment for wounded war veterans" and "have the laudable goal of improving the quality of life for persons suffering from spinal cord injuries, strokes, and traumatic brain injuries." Similarly, the Association of Public-Safety Communications Officials-International, Inc. ("APCO") "recognize[d] the benefits of these important new medical devices," while the Association for Maximum Service Television, Inc. ("MSTV") "agree[d] that it is important to set aside spectrum for the networks that manage these important medical devices."

In view of the substantial and undisputed public interest benefits that MMNs offer,

Congressional leaders, including Senator John F. Kerry and Representative Howard P. "Buck"

McKeon, a ranking member on the House Armed Services Committee, have urged the

Commission to allocate sufficient spectrum and establish rules allowing MMN operation in the

⁸ Letter from Jennifer S. French, Executive Director, Neurotech Network, Inc., to Marlene H. Dortch, Sec'y, FCC, at 1 (Aug. 11, 2009).

⁹ Letter from Gary Okrent to Marlene H. Dortch, Sec'y, FCC, at 1 (Aug. 11, 2009).

¹⁰ Comments of Motorola at 2 (Aug. 11, 2009).

¹¹ Comments of SBE at 4 (Aug. 11, 2009).

¹² Comments of APCO at 2 (Aug. 11, 2009).

¹³ Letter from David Donovan, President, MSTV, to Marlene H. Dortch, Sec'y, FCC, at 1 (Aug. 11, 2009).

413-457 MHz band.¹⁴ Thus, the record in this proceeding reflects overwhelming support for Commission rules to facilitate deployment of a pioneering medical technology that could revolutionize medical treatment and therapy for millions of seriously disabled Americans, fundamentally improve their quality of life, and substantially reduce the skyrocketing costs of their medical care.

II. THE 413-457 MHz BAND IS WITHIN THE FREQUENCY BAND WIDELY RECOGNIZED TO BE MOST SUITABLE FOR RF SIGNAL PROPAGATION WITHIN THE HUMAN BODY

Contrary to Motorola's and the American Radio Relay League, Inc.'s ("ARRL") claims, ¹⁵ both the Commission and the scientific community have found the 413-457 MHz band to be within the narrow range of spectrum that is most suitable for RF signal propagation within the human body. The Commission previously concluded that frequencies below 216 MHz and above 470 MHz are "outside the range of spectrum generally considered to be the most suitable for propagation of radio signals within the human body." Thus, the Commission implicitly determined that frequencies between 216 MHz and 470 MHz are within the optimal range for RF signal propagation within the human body. ¹⁷

¹⁴ See Letter from John F. Kerry, U.S. Senate, to Julius Genachowski, Chairman, FCC, at 1 (Aug. 19, 2009); Letter from Howard P. "Buck" McKeon, U.S. House of Representatives, to Julius Genachowski, Chairman, FCC, at 1 (Aug. 21, 2009).

¹⁵ See Comments of Motorola at 9; Comments of ARRL at 5 (Aug. 11, 2009).

¹⁶ See Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band, Report and Order, 14 FCC Rcd 21040, \P 6 (1999) ("MICS Order").

¹⁷ AMF readily would accept frequencies within the 216-413 MHz band as alternative spectrum for MMN use, but this spectrum does not appear to be a practical option. The bulk of this spectrum (specifically, the 225-400 MHz band) is devoted to various military operations, and the U.S. Department of Defense apparently views it as "the single most critical spectrum resource of the military tactical forces." *See* Bennett Z. Kobb, Wireless Spectrum Finder 91 (2001).

The Commission's conclusion was supported by research and analysis conducted by Medtronic, Inc. ("Medtronic") in support of the Commission's proposal in 1999 to establish the medical implant communications service ("MICS") (now known as the medical device radiocommunication, or "MedRadio," service) in the 402-405 MHz band. In its filings with the Commission, Medtronic demonstrated that frequencies in the lower 400 MHz band are most suitable for use by MICS implant devices because of a combination of factors, including RF signal propagation within the human body, physical size and power consumption of MICS implant devices, a relatively noise-free RF environment, and international frequency compatibility. Specifically, Medtronic stated that given the power consumption and size constraints, the "implant receiver's dynamic range is limited" and, as a result, "operations of the receiver [are limited] to between 216 and 470 MHz." Medtronic further noted that "operation above several hundred MHz introduces more loss into the communications link than can be overcome by a device with a low power budget and operation below 250 MHz introduces more reflection into the communications link than is acceptable."

Both the Commission's and Medtronic's findings have been further supported by AMF's own research and testing. As AMF stated in its comments, AMF-conducted tissue tests confirm that frequencies in the lower 400 MHz band are optimal for RF signal propagation through body

¹⁸ See Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band, Notice of Proposed Rulemaking, 14 FCC Rcd 3659, ¶ 8 n.12 (1999).

¹⁹ *Id.* (citing Medtronic's Petition for Rulemaking, WT Dkt. No. 99-66, RM-9157 (July 28, 1997) and *ex parte* submission).

²⁰ See Comments of Medtronic at 7, Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band, WT Dkt. No. 99-66, RM-9157 (Apr. 9, 1999).

²¹ *Id*.

tissue.²² Specifically, AMF conducted informal tests to evaluate the effectiveness of RF signal propagation through body tissue at 400-416 MHz versus 915 MHz. These tests showed that, at 915 MHz, the increase in tissue loss and decrease in antenna efficiency reduced the effective communication range to 0 meter for signal transmissions with a link margin of approximately 10 dB. In other words, at 915 MHz, an implanted microstimulator would be unable to transmit or receive signals of sufficient strength to or from an external master control unit ("MCU"), even if the two devices are separated by only body tissue. In contrast, at 400-416 MHz, the effective communication range was approximately eight meters for signal transmissions with a link margin of approximately 10 dB. Thus, in the lower 400 MHz band, an implanted microstimulator could transmit and receive signals of sufficient strength to an external MCU from a distance of up to eight meters.

Moreover, Dr. Cedric Walker, a Professor of Biomedical Engineering at Tulane University with more than 35 years of research experience in the design and implantation of neuroprosthetic devices, attested that MMN bandwidth requirements "can only be supported by a carrier in the 400-500 MHz range, as higher frequency carriers have less ability to penetrate skin and tissue."

As AMF further explained in its comments, frequencies in the lower 400 MHz band, as opposed to higher frequencies, would allow MMN systems to utilize miniature batteries, conserve battery power, prolong battery life, and minimize the need to replace the implant devices or to recharge the batteries more than once a day.²⁴ The miniature size and limited

²² See Comments of AMF at 6 (Aug. 11, 2009).

²³ See Letter from Cedric F. Walker, Ph.D., Tulane University, to Marlene H. Dortch, Sec'y, FCC, at 1 (Aug. 11, 2009).

²⁴ See Comments of AMF at 6.

capacity of the batteries are significant factors in the design of MMN implant devices. These factors impose severe constraints on battery power consumption and ultimately on the range of frequencies within which MMN implant devices can operate optimally.

III. ALTERNATIVE SPECTRUM OPTIONS ARE INADEQUATE FOR MMNs

Motorola, ARRL, and the Land Mobile Communications Council ("LMCC") speculate that wireless medical telemetry service ("WMTS") spectrum in the 608-614 MHz band and medical telemetry spectrum above 450 MHz under Part 90 of the Commission's rules are viable spectrum alternatives for MMNs.²⁵ These parties, however, have no apparent experience or expertise in designing or constructing MMNs, and they offer no support for their claims.

It is undisputed that both WMTS spectrum in the 608-614 MHz band and Part 90 medical telemetry spectrum in the 450-470 MHz band are generally congested, populated with other commercial, high-power transmitters, and adjacent to spectrum occupied by high-power UHF TV transmitters. Restricting MMN operations solely or even primarily to these frequencies would render the devices inoperable due to RF congestion and incumbent high power operations on and adjacent to these frequencies. The Commission, in fact, previously found that these frequencies are subject to "significant constraints." Specifically, WMTS spectrum in the 608-614 MHz band "is constrained as a result of radio astronomy quiet zones, including some sites in

²⁵ See Comments of Motorola at 9; Comments of ARRL at 5; Comments of LMCC at 4-5 (Aug. 11, 2009).

²⁶ See, e.g., Comments of Motorola at 3-4; Comments of ARRL at 5.

²⁷ Although AMF supports an allocation for an MMN channel at 451-457 MHz, this channel would be one of four possible channels that could be used by MMN devices. Thus, as discussed in Section IV(A) below, the RF interference environment for the proposed MMN operation will be manageable.

²⁸ See Amendment of Parts 2 and 95 of the Commission's Rules to Create a Wireless Medical Telemetry Service, 15 FCC Rcd 11206, \P 11 (2000).

large markets, and interference from adjacent TV channels."²⁹ The Commission also noted that Part 90 medical telemetry spectrum "is increasingly being used more intensively by existing primary services, thereby posing an increased risk of interference to medical telemetry devices"³⁰

Moreover, the Commission's service and technical rules governing WMTS and Part 90 medical telemetry equipment are designed specifically to accommodate devices used at health care facilities to measure and record patient-related information, rather than mobile medical implant devices that perform more complex FES functions. For example, Section 95.1107 of the Commission's rules restricts WMTS operations to "anywhere within a health care facility," whereas MMN devices are intended to operate wherever the patient may be. Additionally, the bandwidth, out-of-band emission, and power requirements for MMNs are vastly different from those for medical telemetry equipment. Because of these significant technical differences, revising the WMTS and Part 90 rules to accommodate both medical telemetry and MMN devices would be infeasible, if not impossible.

Furthermore, Motorola contends that frequency bands such as the 903-928 MHz band may be "viable options," but only if the "[additional] losses can be overcome with additional

²⁹ *Id*.

 $^{^{30}}$ *Id.* ¶ 3.

³¹ 47 C.F.R. § 95.1107.

³² For example, WMTS devices in the 608-614 MHz band are (1) limited to four channels, each of which is only 1.5 MHz-wide; (2) subject to a field strength limit of 200 mV/m, measured at a distance of 3 meters; and (3) subject to an out-of-band emission limit of 200 μV/m, measured at a distance of 3 meters, for emissions below 960 MHz. *See* 47 C.F.R. § 95.1115(d)(2). In contrast, MMN devices require (1) up to four wideband channels, each of which is approximately 5 MHz-wide; (2) MCU operation at a maximum EIRP of 1 mW; and (3) out-of-band emission limits from 100 μV/m to 200 μV/m, measured at a distance of 3 meters, for emissions between 30 MHz and 960 MHz. *See* Comments of AMF, App. B (proposing revisions to Commission's rules, including Sections 95.633, 95.635, and 95.639).

power."³³ Motorola, however, offers no evidence that this additional power is achievable for MMN microstimulators that must utilize miniature batteries with limited capacity. Additional power would require much larger batteries, which would increase dramatically the overall size of the microstimulator. This, in turn, would compromise many of the key features of the device, such as ease of implantation and the ability to target fine nerves, maximize patient comfort, and minimize the risk of infection. As discussed in Section II above, frequencies above 470 MHz are simply not viable options for purposes of satisfying MMN technical and design requirements.

IV. MMN OPERATION IN THE 413-457 MHz BAND IS COMPATIBLE WITH **INCUMBENT SYSTEMS**

Parties representing incumbent land mobile radio ("LMR"), remote pickup ("RPU") broadcast, and amateur radio services have raised unfounded claims of harmful interference between MMNs and these incumbent services. As AMF explained in both its Petition and Comments, numerous MMN operational factors and techniques serve to mitigate potential interference both from and to incumbent services.³⁴

AMF will further demonstrate the effectiveness of these factors and techniques through comprehensive interference analysis and testing to be conducted jointly with the Joint Spectrum Center ("JSC"), a field office within the U.S. Defense Spectrum Organization, in fiscal year 2010. AMF has entered into an agreement with JSC to perform this analysis and, if required, testing to determine RF compatibility between MMNs and incumbent government operations, including LMR and radiolocation systems, in the 413-450 MHz band. This process is expected to commence near term. AMF expects that the results will satisfy concerns regarding potential

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³³ Comments of Motorola at 10.

³⁴ See AMF Petition for Rulemaking at 18-21; AMF Comments at 8-13.

interference from and to both government and non-government operations, including LMR, radiolocation, RPU, and amateur radio systems.

A. Motorola's Claims Of Harmful Interference To LMR Systems Are Invalid

Contrary to Motorola's claim, ³⁵ MMNs pose no risk of harmful interference *to* incumbent LMR systems. As AMF noted in its Comments, the differences between MMNs and LMR systems with respect to power and bandwidth requirements are among the numerous factors ensuring that MMNs will not cause harmful interference to higher power, narrowband LMR systems. ³⁶

The interference analysis that AMF submitted with its Petition two years ago was preliminary and based upon extremely conservative, worst-case assumptions. Specifically, the analysis (as well as Motorola's interference analysis) was based upon a free space path loss model that is highly conservative and does not account for additional factors that would result in much greater signal losses. The Commission, in fact, has acknowledged that "free space propagation yields conservative results as it is a worst case model" and that "[i]n practice the mobile operating environment will result in losses that exceed those predicted by free space propagation." Moreover, JSC, in connection with the planned MMN interference analysis and testing, has agreed to use an alternative propagation model for incumbent terrestrial systems.

In any event, Motorola's interference calculations are fatally flawed because they rely upon the following assumptions that are erroneous or have no relevance to or significant impact on the results:

³⁵ See Comments of Motorola at 6-9.

³⁶ See AMF Comments at 9-10.

³⁷ See The FCC's Office of Eng'g and Tech. Releases Analysis of AWS-3 Interference Tests, Public Notice, 23 FCC Rcd 14669, App. n.16 (2008).

- (1) Noise bandwidth of LMR receivers: Motorola conceded that "if the same bandwidth is used in the analysis ... it should not impact the results." AMF's preliminary interference analysis, in fact, consistently used the same bandwidth. Thus, by Motorola's own admission, the noise bandwidth used in AMF's preliminary interference analysis should have no impact on the results.
- (2) Duty cycle assumptions: Motorola suggested that the limited duty cycle of the MCU should not be used to reduce the interference power, but also acknowledged that accounting for the limited duty cycle "is valid if the bursts are very short (on the order of tens of micro-seconds) and provided that the 15 dB reduction ... corresponds to the percentage of time the devices are active." Both of these conditions are largely satisfied—the transmit duty cycle of the MCU is approximately 334 microseconds per 11 milliseconds (for a system with 10 to 20 microstimulators), and the estimated 15 dB reduction corresponds to the duration of MCU activity. Thus, Motorola's refusal to account for the limited duty cycle of the MCU is erroneous.
- (3) Ambient noise: Motorola claimed that, based upon a TIA system design bulletin, "it is rare for the total environmental noise to exceed thermal noise at frequencies in the 413-457 MHz band." Motorola's assumption, however, is contrary to the widely accepted ITU-R Recommendation SA 1346, which relied upon the same ambient noise assumption used in AMF's preliminary interference analysis. Under ITU-R Recommendation SA 1346, ambient noise results in a noise floor at the receiver of 20 dB above thermal noise, rather than Motorola's assumed noise floor of 10 dB above thermal noise.

³⁸ See Comments of Motorola at 7.

³⁹ *Id*.

⁴⁰ *Id*.

⁴¹ See MICS Order ¶ 8 n.26 (citing ITU-R Recommendation SA1346).

(4) Antenna gain of LMR stations: Motorola's interference analysis assumed an antenna gain of 7 dBi for LMR base stations, but failed to consider line losses resulting from base station antennas that typically are installed on tall towers or buildings. These line losses should result in a substantial reduction in the effective base station receiving system gain.

Furthermore, the MMN system strategy for preventing interference to (and from) LMR systems includes a dynamic channel switching technique that is triggered by the received signal strength of the LMR transmitter. Consequently, the MCU will change channels and thus avoid causing harmful interference long before a LMR station will receive any harmful interference from the MMN system.⁴²

B. Parties Representing RPU And Amateur Radio Systems Raised No Claim Of Harmful Interference To Those Services

SBE, MSTV, and ARRL raised no claim of harmful interference to RPU and amateur radio systems. ARRL, in fact, concedes that "the combination of the low EIRP levels and the relatively low duty cycle of AMF [MMN devices] makes interference from those devices in particular to Amateur Radio communications in the 420-450 MHz band unlikely generally." Although SBE, MSTV, and ARRL raised concerns regarding harmful interference from incumbent systems to MMNs, these concerns should be satisfied through the joint AMF-JSC interference analysis and, if required, testing that is scheduled to commence in the near term.

⁴² Specifically, when the MCU detects a strong interference signal at or above a threshold level, it will move the system to an available alternate channel. The threshold level corresponds to a proportionally greater separation between the MMN and LMR systems when the LMR station employs antenna gain. The received signal strength to the MMN receiver and the received signal strength to the land mobile receiver are altered to the same extent, thus offering the same degree of protection regardless of antenna gain.

⁴³ See Comments of ARRL at 8.

C. RF Interference in the 451-457 MHz Band Is Manageable

AMF recognizes that the RF interference environment may be highly challenging particularly for MMN operation on the proposed fourth channel at 451-457 MHz because that channel, especially in urban areas, may be congested, populated with other commercial, highpower transmitters, and near (but not immediately adjacent) to spectrum occupied by high-power UHF TV transmitters. Contrary to contentions by Motorola, ARRL, SBE, and LMCC, 44 however, the RF interference environment for the proposed MMN operation will be manageable because the channel at 451-457 MHz is only one of four channels proposed for MMN operation. MMN devices will not require simultaneous use of all four proposed channels. Through dynamic channel switching, MMN devices can avoid using the fourth channel at 451-457 MHz if that channel is determined to be severely degraded. In fact, this fourth channel is intended to be used as a channel of last resort only when the other three channels are unavailable due to severe RF congestion. Thus, AMF does not anticipate that MMN devices actively will use the fourth channel, particularly in urban areas where the fourth channel may be highly congested. In rural areas, however, AMF expects that the fourth channel will be quite useable due to low RF congestion.

V. THE COMMISSION SHOULD ADOPT TECHNICAL REQUIREMENTS THAT MITIGATE POTENTIAL INTERFERENCE BETWEEN MMNs AND OTHER SYSTEMS

The comments of the Cleveland FES Center ("CFC") in support of the Commission's proposed MMN rules confirm that MMN technology is both real and under development by multiple, independent parties.⁴⁵ Because multiple competing suppliers may offer different MMN

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⁴⁴ See Comments of Motorola at 3-4; Comments of ARRL at 5-6; Comments of LMCC at 4; Comments of SBE at 5.

⁴⁵ See Comments of CFC at 1-2 (Aug. 11, 2009).

devices, the Commission should adopt a minimum set of technical requirements designed to ensure RF compatibility between different MMN systems, as well as between MMNs and incumbent systems. These technical requirements are reflected in AMF's proposed MMN rules, as revised and attached to its Comments.⁴⁶

In its comments, CFC proposed certain MMN rules that apparently are intended to allow flexibility in the design and implementation of different MMN devices.⁴⁷ Although this goal is laudable, CFC's proposed rules should be rejected because they would not ensure RF compatibility with other systems. In fact, CFC's proposed definition of "MMN" and proposed rules providing for (1) implant-to-implant communications, (2) no specific channel plan, (3) use of an "open-source" contention protocol, and (4) no particular transmitter power limit would create an unmanageable RF interference environment.

Specifically, CFC's proposed rules would allow implant devices to communicate with each other and to operate without any control by the MCU. This represents a significant departure from the existing MedRadio rules prohibiting implant-to-implant communications and requiring implant devices to operate under the control of a programmer/control transmitter. These MedRadio restrictions properly serve to manage RF transmissions to and from implant devices, and thus should be incorporated into the MMN rules.

Although CFC's proposed use of an "open-source" contention protocol could be workable, its proposal is too vague and indefinite to warrant adoption as an MMN requirement. Furthermore, CFC contends that EIRP limits "should not reflect any particular manufacturers

⁴⁶ See AMF Comments, App. A.

⁴⁷ See Comments of CFC at 2.

⁴⁸ See, e.g., 47 C.F.R. § 95.1209(b).

[sic] communication scheme,"49 but offers no alternative basis for specifying EIRP limits. EIRP limits are critical to preventing harmful interference, and the absence of these limits is simply untenable.

In contrast, AMF's proposed MMN rules are largely based upon the Commission's existing MedRadio rules, and strike a proper balance between allowing flexible spectrum use and ensuring effective interference mitigation. Thus, AMF's proposed rules offer a reasonable regulatory framework for MMNs and should be adopted.

VI. **CONCLUSION**

The record developed in this proceeding provides strong support for allowing MMN operations in the 413-457 MHz band on a secondary basis. Based upon the foregoing, AMF urges prompt Commission action to establish service and technical rules to facilitate deployment of a revolutionary technology that will offer invaluable health and public interest benefits for millions of disabled Americans.

Respectfully submitted,

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⁴⁹ See Comment of CFC at 2.